REMARKS

Claims 1-84 are currently pending. With this amendment, claims 1-4, 6-12, 14-19, 22-32, 48, 72, and 78 have been amended to more particularly recite Applicant's invention and new claims 85-88 have been added. Support for new claims 85-86 is found on page 17, lines 14-15, of the specification. Support for new claim 87 is found in Table 1 on page 5 of the specification where the sensitivity of measurement of the V_4 and V_5 leads is shown to be 90 percent and that the sensitivity of other lead combinations capable of being measured by the claimed methods is shown to be greater than 90 percent. Upon entry of this response, claims 1-88 will be pending. This amendment also corrects a typographical error made in the specification. No new matter has been added by way of the amendments to the specification, amendments to the claims or new claims 85-88. Entry of the foregoing amendments to the specification and claims as well as new claims 85-88 is respectfully requested.

In the March 22, 2006 Office Action, the Examiner:

- objected to claims 5, 13, and 21 for reciting a method rather than an apparatus;
- rejected claims 9-29 under 35 U.S.C. § 112, second paragraph, because they add elements or steps to a base claim that already "consists of" recited elements or steps;
- rejected claim 31 under 35 U.S.C. § 112, second paragraph, for lack of sufficient antecedent basis;
- rejected claims 72-77 under 35 U.S.C. § 101 for allegedly being directed to non-statutory subject matter;
- rejected claims 1-8, 30 and 31 under 35 U.S.C. § 103(a) as being unpatentable over United States Patent Number 4,233,987 to Feingold (hereinafter "Feingold") in view of United States Patent Number 4,883,064 to Olson *et al.* (hereinafter "Olson");
- rejected claims 32, 35, 45 and 47 under 35 U.S.C. § 103(a) as being unpatentable over Feingold and Olson and admitted prior art;
- rejected claims 32, 33, 35-43, 46, 48-63, 65-71, 78, and 80-84 under 35 U.S.C. § 103(a) as being unpatentable over United States Patent Number 5,724,580 to Levin *et al.* (hereinafter "Levin") in view of Olson and Feingold; and
- rejected claims 34, 44, 64, and 79 under 35 U.S.C. § 103(a) as being unpatentable over Levin in view of Olson and Feingold and further in view of United States Patent No. 6,322,504 to Kirshner (hereinafter "Kirshner").

Applicant has amended claim 9 to recite a method of measuring first and second precordial leads without user intervention. Applicant believes that the claim is fully patentable over the prior art cited by the Examiner because none of the art cited by the Examiner, and none of the art that Applicant is aware of, teaches or suggests the use of a first precordial electrode (*e.g.*, V_4) as ground when measuring a second precordial lead (*e.g.*, measuring lead V_5). In the art, right leg is used to measure ground when measuring a precordial lead. Support for the amendments to claim 9 are found in, for example, (i) Section 2.7 of the specification, in which conventional five lead electrocardiogram designs for measuring precordial leads are disclosed, (ii) the fact that right leg serves as ground in lead measurement as is known in the art and as is explained, for example, on page 2, line 19, of the specification and (iii) page 19, lines 10-13, which shows how precordial electrodes can serve as ground to measure leads in the present invention. Claim 88 has been added to recite the combination of claims 1 and 9 wherein left leg has been placed on its own pad, as illustrated, for example, in configuration 1107 of Fig. 11C and described on page 31, lines 1-17, of the specification. Claim 88 is a four pad system that Applicant believes is fully patentable over the prior art cited by the Examiner because none of the art cited by the Examiner, and none of the art that Applicant is aware of, teaches or suggests the use of a first precordial electrode (*e.g.*, V_4) as ground when measuring a second precordial lead (*e.g.*, measuring lead V_5).

THE CLAIM OBJECTIONS SHOULD BE WITHDRAWN

The Examiner objected to claims 5, 13, and 21 for reciting a method rather than an apparatus. Applicant notes that base claim 1 has been amended to recite a method. Therefore claims 5, 13, and 21 should now in fact recite a method rather than an apparatus. Accordingly, Applicant requests that the claim objections be withdrawn.

THE 35 U.S.C. § 112, SECOND PARAGRAPH, REJECTIONS SHOULD BE WITHDRAWN

Claims 9-29. The Examiner rejected claims 9-29 under 35 U.S.C. § 112, second paragraph, because they add elements or steps to a base claim that already "consists of" recited elements or steps. Applicant has amended claims 1, 9, 17 and 22 to address this rejection. Claim 1 now recites a method for electrocardiogram measurement using a first non-conductive pad and a second non-conductive pad comprising enumerated steps. Claims 9, 17, and 22 have been amended to remove the "further consisting" clause. Applicant

submits that with these amendments, claims 9-29 are fully compliant with the requirements of M.P.E.P. Section 2111.03.

Claim 31. The Examiner rejected claim 31 because the phrase "the connector device" lacks antecedent basis. In response, Applicant has replaced the phrase "the connector device" with the phrase "the method".

For the above-identified reasons, Applicant requests that the 35 U.S.C. § 112, second paragraph, rejections of claims 9-29 and 31 be withdrawn.

THE 35 U.S.C. § 101 REJECTION SHOULD BE WITHDRAWN

The Examiner has rejected claims 72-77 under 35 U.S.C. § 101 for being directed to non-statutory subject matter. The Examiner recommended that the claims be amended to recite the elements of the member record as being stored on a tangible computer readable medium. In response, Applicant has amended claim 72 to recite that the member identifier, the personal record, and the ECG data are stored on a tangible computer useable medium. Claims 73-77 depend from claim 72 and thus inherit this claim limitation. Accordingly, Applicant requests that the 35 U.S.C. § 101 rejection of claims 72-77 be withdrawn.

THE 35 U.S.C. § 103 REJECTION OF CLAIMS 1-8, 30 AND 31 SHOULD BE WITHDRAWN

The Examiner rejected claims 1-8, 30 and 31 under 35 U.S.C. § 103(a) as being unpatentable over Feingold in view of Olson. Applicant traverses the rejection in view of claim amendments made. Claim 1 as amended recites a method for electrocardiogram measurement using a first non-conductive pad and a second non-conductive pad in which a first lead and a second lead are measured without user intervention.

Unlike the prior art, including the art cited by the Examiner, the claimed methods use only two electrical pads to measure two different leads without user invention. In the art it is known that measurement of two different leads requires placement of multiple pads. The correct placement of these pads and the correct measurement of leads using these pads requires substantial training. The instant claims recite methods for measuring two different leads using fewer pads and without user intervention. For these reasons, the claimed methods require substantially less medical training than prior art methods. Thus, one of the many advantages of the instant claims is that they provide a solution to obtaining highly sensitive measurements even in the ambulatory setting or in other settings where less medical training is provided.

The Examiner has cited a number of references against the Applicant's claims. However, none of these references teach or suggest the unique reduced pad arrangement that allows for measurement of at least two different leads without user intervention.

The primary reference applied by the Examiner to reject claim 1 is Feingold. However, Feingold does not teach or suggest a two pad system for measuring a first and second lead without user intervention as recited in Applicant's claim 1. Feingold displays a precordial pad similar to the precordial strip disclosed in Figure 3A of Applicant's specification. Figure 3A illustrates the precordial pad of United States patent No. 4,583,549 to Manoli in which the six electrodes are plated on an adhesive pad in a pattern designed to place these electrodes at the correct precordial positions (V_1 through V_6). As discussed on page 6 of Applicant's specification, Manoli contemplates that, considering the range of sizes of individuals, a great percentage of all patients can be tested by the use of three different pad sizes, namely pediatric, medium size adult and large size adult. Rather than using different size pads to cover the precordial positions, Feingold provides perforations between the electrodes so that they can be cut and placed in the precordial positions noted in Figure 2A of Applicant's specification. Thus, Feingold solves the problem of providing a precordial pad that can accommodate different sized subjects. Note, that column 3, lines 3-7, of Feingold states that the electrodes are separated using this perforation in "special circumstances." Column 1, lines 20-24, of Feingold indicates that, consistent with Manoli, these special circumstances are to accommodate different size subjects (adults versus children).

The Examiner states that, because of the perforations between the Feingold electrodes, an individual separated Feingold electrode is inherently capable of being positioned close to the right arm of the subject and therefore functioning as a RA electrode. Applicant has amended claim 1 to positively recite the step of placing a second non-conductive pad at a position that is on or close to the right arm of the subject. Thus, even if the Feingold apparatus is inherently capable of being positioned close to the right arm of the subject, there is absolutely no teaching in Feingold for the act of using the separated electrode as RA in the context of Applicant's claimed method. In other words, Feingold does not teach or suggest the use of an electrode as a RA electrode as positively recited in claim 1 as amended. Moreover, while the separated Feingold electrodes are inherently capable of placement at nonprecordial positions, one of skill in the art, reading Feingold, would understand that the perforations present in Feingold are intended for improved placement of electrodes on the *precordial* positions of the subject, not RA or other nonprecordial positions.

Furthermore, there is no teaching in Feingold to measure two different leads without user intervention.

The Examiner relies on the teachings of Olson to remedy the deficiencies in Feingold. However, like Feingold, Olson does not teach or suggest a two pad solution for measuring a first and second lead without user intervention. Olson uses three pads to measure leads I, II and III. As noted in Table 1 on page 5 of Applicant's specification, leads I, II, and III, by themselves (*e.g.*, without the precordial leads) have very little sensitivity. For example, lead II has a sensitivity of only 33%. Olson does switch between leads I, II and III but does so using a *three* pad system in which each pad has an electrode that is one of RA, LA, and LL. Thus, not only is Olson a low sensitivity apparatus, it uses three pads. Olson does not teach or suggest how to switch between two different leads using a *two* pad system. Moreover, Olson relies on the use of an LA whereas claim 1 does not.

According to the Examiner, one of skill in the art, motivated by the switching between leads I, II and III without user intervention taught by Olson, would apply this switching without user intervention to Feingold. However, even if Olson were applied to Feingold, there is still no teaching or direction on the use of a *two* pad system to measure two leads without user intervention in which one of the pads is placed on RA and the other is either partially or fully precordial. Olson requires three positions, not two, and neither position is partially or fully precordial as set forth in Applicant's claim 1. Feingold teaches a precordial pad in which individual pads can be separated but does not teach or suggest a two pad system in which one of the pads is placed on RA. Of course, the Feingold electrodes can be separated as the Examiner points out. But this in no way renders the specific steps positively recited in claim 1 obvious: Feingold does not teach or suggest a two pad system to measure a first and second lead without user intervention in which one of the pads is RA. The only way to arrive at Applicant's two pad solution is to combine pieces of Feingold and unrelated pieces of Olson with the impermissible hindsight of Applicant's specification.

In rejecting claim 32, the Examiner notes that the placement of a Feingold electrode on RA is obvious in view of Applicant's admitted prior art disclosed in Fig. 3E and page 8 of Applicant's specification in which a 3-electrode ECG system includes RA. However, Fig. 3E and page 8, either alone or in combination with Feingold and Olson, does not render Applicant's claim 1 obvious because itmerely discloses a *three* pad system. Specifically, Fig. 3E does not teach or suggest how to switch between two different leads using a *two* pad system without user intervention. As noted on pages 8 and 9 of Applicant's specification, the modified V_5 system of Fig. 3E is disadvantageous because (i) it is necessary to manually

switch between Lead II and the V_5 lead and select Lead I on a monitor in order to get these two leads and (ii) the modified V_5 system requires placement of three electrodes on three different pads on a subject. Thus, no combination of the modified V_5 system of Fig. 3E (three pads), Olson (three pads), and Feingold (one precordial pad which can be broken into multiple precordial pads) teaches or suggest Applicant's claim 1 unless the impermissible hindsight of Applicant's specification is used.

Claims 2-8, 30 and 31 depend from claim 1 and therefore are patentable over the cited art for at least the reasons discussed above.

Claim 2 is patentable over any combination of Feingold and Olson for the additional reason that the references alone or in combination do not teach or suggest a two pad solution in which a first electrode on the first of the two pads represents any one of the V_4, V_5, or V_6 positions and a second electrode also on the first of the two pads represents LL.

Claim 3 is patentable over any combination of Feingold and Olson for the additional reason that the references alone or in combination do not teach or suggest measurement of the V_4 or a V_5 lead using a two pad solution in which a third electrode that is RA (on the second pad) and a first electrode (on the first pad) placed in a precordial position, when the second electrode (LL) (also on the first pad) is ground.

Claim 4 is patentable over any combination of Feingold and Olson for the additional reason that the references alone or in combination do not teach or suggest a two pad solution in which lead II is measured from a third electrode (RA) and a second electrode (LL) when the first electrode (V_4) is ground.

Claim 5 is patentable over any combination of Feingold and Olson for the additional reason that the references alone or in combination do not teach or suggest a two pad solution in which a first and second lead are measured without user intervention such that the first lead is V_4 or V_5 and the second lead is lead II.

Claim 7 is patentable over any combination of Feingold and Olson for the additional reason that the references alone or in combination do not teach or suggest a two pad solution in which a V_4 lead is measured from a third electrode (RA) and a first electrode (V_4) when a second electrode (V_5) is ground.

Claim 8 is patentable over any combination of Feingold and Olson for the additional reason that the references alone or in combination do not teach or suggest a two pad solution in which a V_5 lead is measured from a third electrode (RA) and a second electrode (V_5) when the first electrode (V_4) is ground.

Claim 30 is patentable over any combination of Feingold and Olson for the additional reason that the references alone or in combination do not teach or suggest a two pad solution in which a first electrode represents V_4 or V_5 and is positioned on V_4 or V_5 of a subject while a second electrode represents LL.

For the above-identified reasons, Applicants request that the 35 U.S.C. § 103(a) rejection of claims 1-8, 30 and 31 be withdrawn.

THE 35 U.S.C. § 103 REJECTION OF CLAIMS 32, 35, 45, AND 47 SHOULD BE WITHDRAWN

The Examiner has rejected claims 32, 35, 45 and 47 under 35 U.S.C. § 103(a) as being unpatentable over Feingold and Olson and admitted prior art. The Examiner claims that a two pad solution for measuring two different leads without user intervention in which one of the pads is RA is obvious in view of the stated prior art (Fig. 3E of the specification). The arrangement of electrodes in Fig. 3E is not the same as what is recited in claim 32. Nor is the arrangement illustrated in Feingold. Yet, the Examiner claims that Fig. 3E provides the motivation for mixing and matching the Feingold electrodes and the Fig. 3E electrodes to arrive at the arrangement recited in claim 32. On page 6 of the March 22, 2006 office, the Examiner states that the motivation for doing so would be to measure Lead II. As discussed below, the combination of Fig. 3E and Feingold would not lead to a device that teaches all the elements of claim 32 if the motivation for such a combination was to measure Lead II.

From line 32 of page of the specification it is known that Lead II = (LL – RA). Claim 32 requires a two pad solution in which one pad is RA and the other pad contains two electrodes. Feingold teaches a pad that contains multiple electrodes. To get Feingold to measure Lead II, one of the Feingold electrodes must be separated using the perforation described in Feingold and placed at RA. The other pad, containing two electrodes would have to then be placed on LL. But, as noted in Figure 5 and page 16, lines 15-16, of the specification LL is below the precordial positions. So, if the second Feingold pad is placed on LL to measure Lead II, the arrangement would not match what is recited in claim 32. In claim 32, a first non-conductive pad has a first electrode and a second electrode disposed thereon, where the first electrode represents any one of V_4, V_5, or V_6 and the second electrode is either (i) positioned on the subject below the first electrode in order to represent left leg (LL) or (ii) is placed on a line on the subject defined by the V_4, V_5, and V_6 precordial

positions. The second Feingold pad cannot both be on the LL position and the precordial positions. It has to be one or the other. Furthermore, rotating the Feingold patent 90 degrees from the position illustrated in Fig. 1 of Feingold will not work because the pad will not longer have the correct shape to adhere to the chest. This is because, as noted throughout Feingold (*e.g.*, title, abstract, each independent claim, all figures, column 1, lines 28-30) the pad has a curvelinear shape which is designed, as illustrated in Fig. 3, to attach to the curved portion (*e.g.*, precordial portion) of the chest. For these reasons, the very motivation that the Examiner posits for combining the modified V_5 arrangement of Fig. 3E with Feingold leads to a pad combination that cannot possibly comply with all the claim limitations of claim 32. The Feingold pad with two electrodes must either be on LL or on the precordial positions. It cannot be on both. Thus, the presence of an RA electrode in the three pad modified V_5 system of Applicant's Fig. 3E would not have led someone of skill in the art to arrange the precordial electrodes in the manner set forth in claim 32.

Claims 35, 45 and 47 depend from claim 32 and are patentable over the cited art for at least the same reasons that claim 32 is patentable over the cited art. Thus, for the above-identified reasons, Applicants request that the 35 U.S.C. § 103(a) rejection of claims 32, 35, 45 and 47 under 35 U.S.C. § 103(a) as being unpatentable over Feingold and Olson and admitted prior art be withdrawn.

THE 35 U.S.C. § 103 REJECTION OF CLAIMS 32, 33, 35-43, 46, 48-63, 65-71, 78, AND 80-84 SHOULD BE WITHDRAWN

The Examiner rejected claims 32, 33, 35-43, 46, 48-63, 65-71, 78, and 80-84 under 35 U.S.C. § 103(a) as being unpatentable over Levin in view of Olson and Feingold.

Regarding claims 32, 33, 35-43, and 46. The Examiner notes that Levin does not disclose the electrode lead configurations claimed by Applicant. However, the Examiner reasons that this deficiency in Levin is remedied by Feingold because "Feingold discloses an ECG electrode embodiment that includes first and second electrodes on a single pad placed in the V_4, V_5, or V_6 positions, and a separate individually placed electrode." In response, Applicant has amended claim 32 to positively recite that the analyzing of electrocardiogram measurement is taken when said second non-conductive pad is placed on or close to the right arm of said subject. Feingold does not disclose placement of an electrode on the right arm. Moreover, the three pad arrangement of Olson nor the three pad arrangement of Fig. 3E of Applicant's specification remedies this deficiency in Feingold for the reasons articulated

above with respect to the rejection of claim 1 in view of Feingold and Olson. Claims 33, 35-43, and 46 depend from claim 32 and are patentable over the cited art for at least the same reasons that claim 32 is patentable over the cited art.

Regarding claims 48-63, 65-71, and 84. Applicant has amended claims 48 and 84 to positively recite instructions for analyzing data collected at a time when said second non-conductive pad is placed on or close to the right arm of said subject. Feingold does not disclose placement of an electrode on the right arm. Moreover, the three pad arrangement of Olson nor the three pad arrangement of Fig. 3E of Applicant's specification remedies this deficiency in Feingold for the reasons articulated above with respect to the rejection of claim 1 in view of Feingold and Olson. Claims 48-63 and 65-71 depend from claim 48 and are patentable over the cited art for at least the same reasons that claim 48 is patentable over the cited art.

Regarding claims 78, and 80-83. Applicant has amended claim 78 to positively recite that the electrocardiogram measurement is taken at a time when the third electrode is positioned on or close to the right arm of said subject. No combination of the cited art teaches or suggests this claim limitation when taken together with the original claim limitations of claim 78. Claims 80-83 depend from claim 78 and are therefore patentable over the cited art for the same reasons that claim 78 is patentable over the cited art.

Thus, for the above-identified reasons, Applicant requests that the 35 U.S.C. § 103(a) rejection of claims 32, 33, 35-43, 46, 48-63, 65-71, 78, and 80-84 over Levin in view of Olson and Feingold be withdrawn.

THE 35 U.S.C. § 103 REJECTION OF CLAIMS 34, 44, 64, AND 79 SHOULD BE WITHDRAWN

The Examiner has rejected claims 34, 44, 64, and 79 under 35 U.S.C. § 103 in view of Levin, Olson, Feingold and Kirshner. These rejected claims each ultimately depend on one of claims 32, 48, and 78. Kirshner fails to remedy the deficiencies identified above in rendering claims 32, 48, and 78 obvious. Thus, claims 34, 44, 64, and 79 are patentable over the cited art for at least the same reasons that claims 32, 48, and 78 are patentable over the cited art. Accordingly, Applicants request that the 35 U.S.C. § 103 rejection of claims 34, 44, 64, and 79 be withdrawn.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks into the file of the above-identified application.

Respectfully submitted,

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